XYZAL ALLERGY 24HR- levocetirizine dihydrochloride tablet
Chattem, Inc.

Xyzal Allergy 24HR

Xyzal Allergy 24HR Tablet

Drug Facts

Active ingredient

(in each tablet)

Levocetirizine dihydrochloride 5 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever or other respiratory allergies:
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat

Warnings

Do not use
- if you have kidney disease
- if you have ever had an allergic reaction to this product or any of its ingredients or to an antihistamine containing cetirizine

Ask a doctor before use if you have
- ever had trouble urinating or emptying your bladder

When using this product
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if
- you have trouble urinating or emptying your bladder
- an allergic reaction to this product occurs. Seek medical help right away.

If pregnant or breast-feeding:

- if breast-feeding: not recommended
- if pregnant: ask a health professional before use

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

adults 65 years of age and older	■ ask a doctor
adults and children 12-64 years of age	■ take 1 tablet (5 mg) once daily in the evening ■ do not take more than 1 tablet (5 mg) in 24 hours ■ ½ tablet (2.5 mg) once daily in the evening may be appropriate for less severe symptoms
children 6-11 years of age	■ take ½ tablet (2.5 mg) once daily in the evening ■ do not take more than ½ tablet (2.5 mg) in 24 hours
children under 6 years of age	■ do not use
consumers with kidney disease	■ do not use

(Note: Age ranges are bolded in the draft container labeling for tablet bottle)

Other information

- store between 20° and 25°C (68° and 77°F)
- *(if blister)* safety sealed: do not use if carton was opened or if individual blister unit is open or torn

(if bottled) safety sealed: do not use if carton was opened or if printed foil inner seal on bottle is torn or missing

(if stretch card) safety sealed: do not use if sealed package was torn or opened, or if printed foil inner seal on bottle is torn or missing

Inactive ingredients

Colloidal anhydrous silica, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, titanium dioxide

Questions or comments?

call **1-800-633-1610**

PRINCIPAL DISPLAY PANEL

NDC 41167-3510-0
XYZAL
Allergy 24HR
5 mg
10 Tablets

PRINCIPAL DISPLAY PANEL

NDC 41167-3510-1
XYZAL
Allergy 24HR
5 mg
35 Tablets

XYZAL ALLERGY 24HR

levocetirizine dihydrochloride tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41167-3510
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LEVOCETIRIZINE DIHYDROCHLORIDE (UNII: SOD6A38AGA) (LEVOCETIRIZINE - UNII:6U5EA9RT2O)	LEVOCETIRIZINE DIHYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	OVAL	**Size**	8mm
Flavor		**Imprint Code**	X;X
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-3510-0	1 in 1 CARTON	03/10/2017	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41167-3510-1	1 in 1 CARTON	03/10/2017	
2		35 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:41167-3510-2	1 in 1 CARTON	03/10/2017	
3		55 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:41167-3510-3	1 in 1 CARTON	03/10/2017	
4		80 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:41167-3510-4	2 in 1 CARTON	03/10/2017	
5		55 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA209089	03/10/2017	

Labeler - Chattem, Inc. (003336013)

Revised: 3/2023 Chattem, Inc.